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03-18-02

PTO/SB/05 (03-01)

A

 Approved for use through 10/31/2002. OMB 0651-0032
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. 1.53(b))

| | |
|------------------------|--|
| Attorney Docket No. | 4498C1 |
| First Inventor | Christian A. Heid |
| Title | EXTERNAL CONTROL REAGENTS FOR NUCLEIC ACID AMPLIFICATION |
| Express Mail Label No. | EL 897 622 435 US |

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO:

 Assistant Commissioner for Patents
 Box Patent Application
 Washington, DC 20231

1. ☒ Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original, and a duplicate for fee processing)
2. ☐ Applicant claims small entity status.
See 37 C.F.R. 1.27.
3. ☒ Specification [Total Pages 32]
(preferred arrangement set forth below)
 - Descriptive title of the Invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to sequence listing, a table, or a computer program listing appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
4. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets 8]
5. Oath or Declaration [Total Pages 3]
 a. ☐ Newly executed (original or copy)
 b. ☒ Copy from a prior application (37 C.F.R. § 1.63(d))
(for continuation/divisional with Box 18 completed)
 i. ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).
6. ☒ Application Data Sheet. See 37 C.F.R. 1.76.

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 a. ☒ Request to use Computer Readable Copy (CRF) from parent application
 b. Specification Sequence Listing on:
 i. ☐ CD-ROM or CD-R (2 copies); or
 ii. ☒ paper
 c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 C.F.R. § 3.73(b) Statement ☐ Power of Attorney (when there is an assignee)
11. ☐ English Translation Document (if applicable)
12. ☒ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503) (Should be specifically itemized)
15. ☐ Certified copy of Priority Document(s) (if foreign priority is claimed)
16. ☐ Certified Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☐ Other:

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 C.F.R. 1.76.

☒ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No. 09/645,959 filed August 24, 2000

Prior application information:

Examiner: Tung, J.Group Art Unit: 1656

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

☒ Customer Number or Bar Code Labelor ☐ Correspondence address below

22896

(Insert Customer No., or Attach bar code label here)

| | | | | | |
|---------|--------------------------|-----------|--------------|----------|--------------|
| Name | Alex Andrus | | | | |
| Address | Applied Biosystems | | | | |
| | 850 Lincoln Centre Drive | | | | |
| City | Foster City | State | California | Zip Code | 94404 |
| Country | US | Telephone | 650-570-6667 | Fax | 650-638-6677 |

| | | | |
|-------------------|-------------|-----------------------------------|----------------|
| Name (Print/Type) | Alex Andrus | Registration No. (Attorney/Agent) | 44,509 |
| Signature | | Date | March 14, 2002 |

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231.

30732_1

FEE TRANSMITTAL for FY 2002

Patent fees are subject to annual revision.

Complete if Known

| | |
|----------------------|---------------------------|
| Application Number | To be assigned |
| Filing Date | March 15, 2002 (herewith) |
| First Named Inventor | Christian A. Heid et al. |
| Examiner Name | Tung, J. |
| Group Art Unit | 1656 |
| Attorney Docket No. | 4498C1 |

TOTAL AMOUNT OF PAYMENT (\$ 938.00)

METHOD OF PAYMENT (check one)

1. ☒ The Commissioner is hereby authorized to charge indicated fees and credit any overpayment to
- Deposit Account Number 01-2213
- Deposit Account Name Applied Biosystems
- ☒ Charge any Additional Fee Required Under 37 CFR 1.16 and 1.17
- ☐ Applicant claims small entity status See 37 CFR 1.27

2. ☐ Payment Enclosed:
- ☐ Check ☐ Credit card ☐ Money ☐ Other Order

FEE CALCULATION

1. BASIC FILING FEE

| Large Entity | Small Entity | Fee Code (\$) | Fee Code (\$) | Fee Description | Fee Paid |
|--------------|--------------|---------------|---------------|------------------------|-------------|
| 101 | 740 201 | 370 | | Utility filing fee | 740.00 |
| 106 | 330 206 | 165 | | Design filing fee | |
| 107 | 510 207 | 255 | | Plant filing fee | |
| 108 | 740 208 | 370 | | Reissue filing fee | |
| 114 | 160 214 | 80 | | Provisional filing fee | |
| SUBTOTAL (1) | | | | | (\$ 740.00) |

2. EXTRA CLAIM FEES

| Total Claims | Extra Claims | Fee from below | Fee Paid |
|--------------------|--------------|----------------|----------|
| 31 | 20**= 11 | 18 00 | 198.00 |
| Independent Claims | 1 -3 **= 0 | 0 | 0 |
| Multiple Dependent | | 0 | 0 |

**or number previously paid, if greater, For Reissues, see below

| Large Entity | Small Entity | Fee Code (\$) | Fee Code (\$) | Fee Description |
|--------------|--------------|---------------|---------------|--|
| 103 | 18 203 | 9 | | Claims in excess of 20 |
| 102 | 84 202 | 42 | | Independent claims in excess of 3 |
| 104 | 280 204 | 140 | | Multiple dependent claim, if not paid |
| 106 | 84 206 | 42 | | ** Reissue independent claims over original patent |
| 110 | 18 210 | 9 | | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) (\$ 198.00)

FEE CALCULATION (continued)

| Large Entity | Small Entity | Fee Code (\$) | Fee Code (\$) | Fee Description | Fee Paid |
|----------------------|--------------|---------------|---------------|--|----------|
| 105 | 130 205 | 65 | | Surcharge - late filing fee or oath | |
| 127 | 50 227 | 25 | | Surcharge - late provisional filing fee or cover sheet. | |
| 139 | 130 139 | 130 | | Non-English specification | |
| 147 | 2520 147 | 2520 | | For filing a request for ex parte reexamination | |
| 112 | 920* 112 | 920* | | Requesting publication of SIR prior to Examiner action | |
| 113 | 1840* 113 | 1840* | | Requesting publication of SIR after Examiner action | |
| 115 | 110 215 | 55 | | Extension for reply within first month | |
| 116 | 400 216 | 200 | | Extension for reply within second month | |
| 117 | 920 217 | 460 | | Extension for reply within third month | |
| 118 | 1440 218 | 720 | | Extension for reply within fourth month | |
| 128 | 1960 228 | 980 | | Extension for reply within fifth month | |
| 119 | 320 219 | 160 | | Notice of Appeal | |
| 120 | 320 220 | 160 | | Filing a brief in support of an appeal | |
| 121 | 280 221 | 140 | | Request for oral hearing | |
| 138 | 1510 138 | 1510 | | Petition to institute a public use proceeding | |
| 140 | 110 240 | 55 | | Petition to revive - unavoidable | |
| 141 | 1280 241 | 640 | | Petition to revive - unintentional | |
| 142 | 1280 242 | 640 | | Utility issue fee (or reissue) | |
| 143 | 460 243 | 230 | | Design issue fee | |
| 144 | 620 244 | 310 | | Plant issue fee | |
| 122 | 130 122 | 130 | | Petitions to the Commissioner | |
| 123 | 50 123 | 50 | | Petitions related to provisional applications | |
| 126 | 180 126 | 180 | | Submission of Information Disclosure Stmt | |
| 581 | 40 581 | 40 | | Recording each patent assignment per property (times number of properties) | |
| 146 | 740 246 | 370 | | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 149 | 740 249 | 370 | | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 179 | 740 279 | 370 | | Request for Continued Examination (RCE) | |
| 169 | 900 169 | 900 | | Request for expedited examination of a design application | |
| Other fee (specify), | | | | | |
| SUBTOTAL (3) | | | | | (\$) |

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)

SUBMITTED BY

| Name (Print/Type) | Registration No. (Attorney/Agent) | Telephone |
|-------------------|-----------------------------------|--------------|
| Alex Andrus | 44,509 | 650-638-5607 |
| Signature | Date | |
| | March 14, 2002 | |

WARNING:

Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

CERTIFICATION UNDER 37 CFR 1.10

Express Mail Number: EL 897 622 435 US

Date of Deposit: March 15, 2002

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Box: Patent Application, Washington, D.C. 20231.

Cheri Gomez

(Print Name of Person Mailing Application)

Cheri Gomez

(Signature of Person Mailing Application)

Docket No. 4498C1

**Transmittal of Continuation Patent Application
For Filing Under 37 CFR 1.53(b)**

PRIOR APPLICATION: Examiner: Tung, J. Art Unit: 1656

Assistant Commissioner for Patents

Box: Patent Application
Washington, D.C. 20231

Sir:

This is a request for filing a ☒ continuation ☐ divisional application under 37 CFR 1.53(b), of pending prior application serial no. 09/645,959 filed on August 24, 2000 by Christian A. Heid and Kenneth J. Livak entitled:

External Control Reagents for Nucleic Acid Amplification

1. Enclosed are:

- ☒ One stamped, self-addressed postcard for PTO datestamp.
- ☒ Certificate of Express Mail.
- ☒ One utility patent application containing text pages 1 - 32 and
- ☒ 8 sheets of ☒ formal ☐ informal drawings.
- ☒ Application Data Sheet.
- ☒ Copy of executed Declaration of Inventorship from parent application serial no. 09/645,959.
- ☐ Sequence Listing printout, Request to Use from prior application, and matching Declaration.
- ☐ A Preliminary Amendment.
- ☐ A new Power of Attorney.

2. Amendment

- ☐ Please enter the enclosed Preliminary Amendment before calculating the filing fee. It is understood that only amendments reducing the number of claims will be entered for this purpose.
- ☐ Please cancel original claims _____, inclusive, before calculating the filing fee. (At least one original independent claim should be retained for filing purposes.)
- ☒ Amend the specification by inserting before the first line the sentence: -- This application is a continuation of application serial no. 09/645,959 filed August 24, 2000, now pending, which is incorporated herein by reference. --

3. Extension of Time

- ☐ A petition for extension of time has been filed in the parent to extend the pendency of the parent to _____ (copy enclosed).

1000738-031502

- ☒ **Conditional Petition for Extension of Time:** An Extension of Time is requested to provide for timely filing *if* required to establish copendency with the parent after all papers filed herewith have been considered.

4. **Prior Documents Still in Effect**

- ☒ This application and parent application Serial No. 09/645,959 filed August 24, 2000 are assigned of record to PE Corporation (NY).
- ☒ Power of attorney in the above-identified prior application is to Alex Andrus, Ph.D., Reg. No. 44,509, and the other attorneys or agents identified therein.

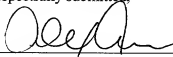
5. **Fees**

The filing fee is calculated below taking into account any amendments in section 2 above:

| FOR | NUMBER FILED | NUMBER EXTRA | RATE | FEE |
|---|-----------------|-----------------|--------|----------|
| TOTAL CLAIMS | 31 - 20 | 11 | X \$18 | \$198.00 |
| INDEPENDENT CLAIMS | 1 - 3 | 0 | X \$84 | \$ 0.00 |
| BASIC FEE | | | | \$740.00 |
| Multiple Dependency Fee If Applicable \$280.00 | | | | |
| Total | | | | |
| 50% Reduction for Independent Inventor, Non-profit Organization or Small Business Concern | | | | |
| TOTAL FILING FEE | | | | \$938.00 |

- ☒ The Commissioner is hereby authorized to charge the filing fee, any deficiency in fees under 37 CFR 1.16 and 1.17, or any other fees necessary for timely filing of this application, or credit any overpayment to Deposit Account No. 01-2213. A duplicate copy of this sheet is enclosed.
- ☐ A check in the amount of \$ _____ is enclosed.
- ☐ Filing fee to be submitted in response to anticipated receipt of Notice to File Missing Parts.
DO NOT CHARGE DEPOSIT ACCOUNT.

Respectfully submitted,



Alex Andrus, Reg. No. 44,509

Dated: March 14, 2002

Correspondence Address:

Customer Number 22896



Applied Biosystems
Patent Department M/S 432-2
850 Lincoln Centre Drive
Foster City, California 94404
Telephone: 650-638-5607

Facsimile: 650-638-6677

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of) Group Art Unit: 1656
)
 Heid and. Livak) Examiner: Tung, J.
)
 Serial No.: To be assigned)
)
 Filed: March 15, 2002 (herewith))
)
 For: **EXTERNAL CONTROL REAGENTS FOR**)
NUCLEIC ACID AMPLIFICATION)

| |
|--|
| <p align="center">CERTIFICATE OF MAILING</p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" on</p> <p>Date: <u>MARCH 15, 2002</u></p> <p>Name: <u>Cheri Gomez</u></p> <p>Signature: <u>Cheri Gomez</u></p> |
|--|

**REQUEST TO USE THE COMPUTER READABLE FORM (CRF) OF THE
SEQUENCE LISTING FROM THE PARENT APPLICATION**

Assistant Commissioner for Patents
 Washington, D.C. 20231

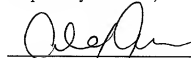
Sir:

The Sequence Listing in the present application is identical to that filed in parent application serial no. 09/645,959 filed August 24, 2000. In accordance with the provisions of 37 C.F.R. § 1.821(e), Applicants request that the compliant computer-readable form of the Sequence Listing that was submitted in parent application no. 09/645,959 on August 24, 2000 be used as the computer-readable form for the present application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the computer-readable form that will be used for the present application. The paper copy of the Sequence Listing enclosed herewith is identical to the computer readable copy filed in the parent application.

No fees are believed due in connection with this response and the enclosed papers. However, the Commissioner is authorized to charge any necessary fee to Deposit Account No. 01-2213. Any deficiency or overpayment should be charged or credited to this deposit account.

Respectfully submitted,

Date: March 14, 2002



Alex Andrus, Reg. No. 44,509
 Agent for Applicants

Correspondence Address

Customer Number 22896
 APPLIED BIOSYSTEMS
 850 Lincoln Centre Drive
 Foster City, CA 94404
 (650) 638-5607 (Phone)
 (650) 638-6677 (Fax)

20090738-031502

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of) Group Art Unit: 1656
)
 Heid and Livak) Examiner: Tung, J.
)
 Serial No.: To be assigned)
)
 Filed: March 15, 2002 (herewith))
)
 For: **EXTERNAL CONTROL REAGENTS FOR**)
NUCLEIC ACID AMPLIFICATION)
)
)
)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being
 deposited with the United States Postal Service
 "Express Mail Post Office to Addressee" on

Date: March 15, 2002Name: Cheri GomezSignature: Cheri GomezSTATEMENT UNDER 37 CFR § 1.821

Assistant Commissioner for Patents
 Washington, D.C. 20231

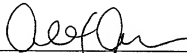
Sir:

I, Alex Andrus, declare and affirm as follows:

1. I am an agent for the applicant.
2. In accordance with the provisions of 37 C.F.R. § 1.821(f), I hereby state that the Sequence Listing information recorded in computer readable form in parent application US Serial No. 09/645,959 is identical to the written sequence listing submitted herewith.
3. In accordance with the provisions of 37 C.F.R. § 1.821(g), I hereby state that this submission does not include new matter.

Respectfully submitted,

Date: March 14, 2002


 Alex Andrus, Reg. No. 44,509
 Agent for Applicants

Correspondence Address

Customer Number 22896
 APPLIED BIOSYSTEMS
 850 Lincoln Centre Drive
 Foster City, CA 94404
 (650) 638-5607 (Phone)
 (650) 638-6677 (Fax)